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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,694	09/30/2003	Michael Brines	10165-027-999	7980
7590 09/12/2006 FREDERICK J. HAMBLE, ESQ. 712 KITCHAWAN ROAD OSSINING, NY 10562			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
DATE MAILED: 09/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,694	<b>Applicant(s)</b> BRINES ET AL.	
	<b>Examiner</b> Ruixiang Li	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 33 (in part), 34 (in part), 37-41 (in part), 43 (in part), 45-47 (in part), and 49 (in part), drawn to a method for identifying a compound that modulates a tissue protective activity, comprising measuring the level of tissue protective cytokine receptor complex activity by measuring the binding of the test compound to the tissue protective cytokine receptor complex, classified in class 435, subclass 7.1.
- II. Claims 5-10, 16-20 (in part), 29-32 (in part), 43-50 (in part), drawn to a method for identifying a compound that modulates a tissue protective activity, comprising measuring the tissue protective cytokine receptor complex activity by a cell proliferative assay, classified in class 435, subclass 4.
- III. Claims 11, 12, 16-20 (in part), 29-32 (in part), 43-50 (in part), drawn to a method for identifying a compound that modulates a tissue protective activity, comprising contacting a test compound with a cell which is recombinantly engineered to express an EPO receptor and a  $\beta$  common receptor polypeptide measuring the tissue protective cytokine receptor complex activity by a cell proliferative assay, classified in class 435, subclass 4.
- IV. Claims 13, 14, 16-20 (in part), 31 (in part), 32 (in part), 43-50 (in part), drawn to a method for identifying a compound that modulates a tissue protective activity, comprising contacting a test compound with a tissue protective cytokine receptor

complex-expressing cell, wherein said cell is transformed with a nucleic acid comprising a nucleotide sequence that encodes a reporter gene, classified in class 435, subclass 6.

V. Claim 15, 16-20 (in part), 43-50 (in part), drawn to a method of identifying a compound that modulates a tissue protective activity, comprising contacting a test compound with a cell comprising (i) a first fusion protein comprising the DNA binding domain of a transcriptional activator and a first tissue protective cytokine receptor polypeptide and (ii) a second fusion protein comprising an activation domain of a transcriptional activator and a second tissue protective cytokine receptor, classified in class 435, subclass 6.

VI. Claim 21, drawn to a method of identifying a compound that modulates the activity of a tissue protective cytokine receptor complex, comprising determining the level of activity of a tissue protective cytokine receptor complex by measuring the level of reporter gene expression in a cell of a modified yeast strain, classified in class 435, subclass 5.

VII. Claims 22-27, 31-41 (in part), 43-50 (in part), drawn to a method for identifying a compound that binds to a tissue protective cytokine receptor complex, classified in class 435, subclass 7.1.

VIII. Claim 28, 29-41 (in part), 43-50 (in part), drawn to a method for identifying a compound that modulates the interaction between a tissue protective cytokine receptor complex and its ligand by measuring the tissue protective cytokine receptor complex activity, classified in class 435, subclass 5.

IX. Claim 42, 43-50 (in part), drawn to a method for identifying a compound that binds a tissue protective cytokine receptor complex, comprising contacting a test compound with a ligand-binding tissue protective receptor complex fragment comprising at least one EPO receptor extracellular domain and at least one  $\beta$  common receptor extracellular domain fused to an Fc fragment attached to a solid support, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other for the following reasons. Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case, the different inventions are drawn to completely different methods each having completely different method steps and having completely different outcomes. Thus, the methods are exclusive and require non-cohesive searches and considerations.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

Art Unit: 1646

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

*Ruixiang Li*

Ruixiang Li, Ph.D.  
Primary Examiner  
June 6, 2006

RUIXIANG LI, PH.D.  
PRIMARY EXAMINER